

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON**

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION THIS DOCUMENT RELATES TO: ALL PLAINTIFFS LISTED IN EXHIBIT A TO PLAINTIFFS' NOTICE OF ADOPTION	Master File No. 2:12-MD-02327 MDL 2327 JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
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**MEMORANDUM IN RESPONSE TO PLAINTIFFS' MOTION TO EXCLUDE
OPINIONS AND TESTIMONY OF CHRISTOPHER RAMSEY, M.D.**

In Wave 3 of this litigation, Plaintiffs adopt the *Daubert* motion they filed as to the general-causation opinions of Christopher Ramsey, M.D. in Wave 1. *See* Pls.' Notice of Adoption (Dkt. 2786). The Court has ruled on that Wave 1 motion. *See In re Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4582227 (S.D.W. Va. Sept. 1, 2016). Defendants Ethicon, Inc., Johnson & Johnson, and, where applicable, Ethicon LLC (Ethicon) respectfully request that this Court again deny Plaintiffs' motion for the reasons expressed in Ethicon's Wave 1 response (Dkt. 2263) incorporated here and as supplemented by the reasons set forth below, and in accordance with this Court's September 1, 2016 Memorandum Opinion and Order.

ARGUMENTS AND AUTHORITIES

I. Dr. Ramsey is qualified to provide safety and efficacy opinions.

Plaintiffs assert the identical arguments and record regarding Dr. Ramsey's opinions on the safety and efficacy rates of mesh products. This Court has already rejected Plaintiffs' argument and found that Dr. Ramsey "has extensive experience with mesh products," and is thus

qualified to offer expert testimony about the safety and efficacy of Ethicon's mesh products. *In re Ethicon, Inc.*, 2016 WL 4582227, at *3. Nothing has changed since this ruling and Plaintiffs have provided no reason to depart from it. The ruling for the Wave 3 cases should be the same.

II. Dr. Ramsey's safety and efficacy opinions are based on a reliable methodology.

A. Dr. Ramsey relied on medical literature he regularly reviews; his opinions are not based solely on literature provided to him by Ethicon.

This Court has made clear that an expert's reliance on peer-reviewed scientific literature, as Dr. Ramsey does here, is an acceptable methodology. *Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, 552 (S.D.W. Va. 2014) ("[T]he review of other professionals' research can form a sound and reliable basis for an expert opinion. Here, [the expert] conducted a thorough review of others' medical research in establishing his opinions."); *see also generally* Ex. G to Pls.' Mot. (Dkt. 2117-7), Ramsey Report (referencing scientific literature throughout his report to support his opinions); Ex. 3, Reliance List in Addition to Materials Referenced in Report. Indeed, Dr. Ramsey regularly reviews medical literature in his field to keep current, and has consistently analyzed his own clinical results and compared them to the published medical literature. Ex. 2, Ramsey 4/7/16 Dep. Tr. 391:24-392:5. Dr. Ramsey also reads the *Journal of Urology*, *Society of Robotic Surgeons*, and the *Gold Journal*. Ex. 1, Ramsey 4/6/16 Dep. Tr. 99:19-100:1. Thus, Dr. Ramsey brings the same "intellectual rigor" in testifying as he employs outside the courtroom. *See Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999).

Yet Plaintiffs rely on isolated excerpts of Dr. Ramsey's deposition testimony and then, taking them out of context, argue that the literature relied upon is that solely provided to him by Ethicon. *See* Pls.' Mem. (Dkt. 2118) at 10-14. Ethicon acknowledges that this Court stated that Dr. Ramsey "focused mostly on medical literature provided by Ethicon" and such a foundation "is shaky." *In re Ethicon, Inc.*, 2016 WL 4582227, at *3, but, as Dr. Ramsey explained during

his deposition, while “most”—meaning, *not all*—of the literature he relied on in his report was provided by counsel, he had already come across almost all of the articles during the course of his clinical practice:

- Q. How did you get the medical literature?
- A. Oh, from -- the medical literature?
- Q. Yes.
- A. Those are published in our medical journals.
- Q. How did you get them?
- A. By reading the journals, by going to conferences.
- Q. Okay. Turn to page -- so you actually went and retrieved these articles listed in the medical --
- A. So -- most of these were given to me, but I --
- Q. Most of these were given to you by Ethicon?
- A. -- but I knew what they -- I knew what a lot of them are.

Ex. 1, Ramsey 4/6/16 Dep. Tr. 55:17-56:9. As shown, Dr. Ramsey’s review of medical literature is not limited to literature provided to him by Ethicon. Instead, he regularly reviews the literature as part of his regular practice of keeping current with the literature in his field. Moreover, Dr. Ramsey has held his opinions—which have not changed—before this litigation:

- Q: The opinions that you intend to express about the safety and efficacy of the TVT products, are those opinions that you have held for many years while you were using those devices?
- A. Yes.
- Q. Are those just opinions you came up with for purposes of litigation?
- A: No.

Ex. 2, Ramsey 4/7/16 Dep. Tr. 395:13-21.

Plaintiffs also take issue with Dr. Ramsey's opinions because they have not been published or subjected to peer review and that he has not participated in clinical studies. *See* Pls.' Mem. (Dkt. 2118) at 4-5. As this Court recognized, observations made by surgeons in their clinical practice are "obviously" not the "type of opinion [that is] subject to testing or peer review." *Mathison v. Boston Scientific Corp.*, No. 2:13-cv-05851, 2015 WL 2124991, at *29 (S.D.W. Va. May 6, 2015). Even so, "[p]ublication (which is but one element of peer review) is not a *sine qua non* of admissibility; it does not necessarily correlate with reliability." *Daubert*, 509 U.S. at 593. So too this Court has recognized that, where an expert relies on the published work of others, publication "is not dispositive." *Trevino v. Boston Scientific Corp.*, No. 2:13-cv-01617, 2016 WL 1718836, at *31 (S.D.W. Va. Apr. 28, 2016). It therefore follows that merely because Dr. Ramsey has not published his opinions does not make his safety and efficacy opinions unreliable.

B. Dr. Ramsey's extensive clinical experience is reliable basis to form his opinion that TVT is safe and effective.

Ethicon acknowledges that this Court has reserved ruling on whether Dr. Ramsey's clinical experience is a reliable methodology to give the safety and efficacy opinions he seeks to offer here, noting that an expert relying on clinical experience alone "must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts." *In re Ethicon, Inc.*, 2016 WL 4582227, at *3, quoting Fed. R. Evid. 702 advisory committee's note to 2000 amendment.

Dr. Ramsey does not limit his methodology to his experience and, as discussed, relies on his regular review of the medical literature as well as his clinical experience. Even if that were not the case, his clinical experience is a sufficiently reliable basis from which to form the safety and efficacy opinions he offers here. Specifically, Dr. Ramsey testified that he treats mesh

complications and performs mesh removal surgeries, Ex. 1, Ramsey 4/6/16 Dep. Tr. 71:21-72:5, which has allowed him to directly observe or hear about from other surgeons—or not—differences between laser and mechanical cut mesh and complications with the TVT, including erosion, curling, roping, or fraying:

Q: Did you notice any loss of particles from the mesh when you used TVT products?

A: No.

Q: Did you notice any fraying of the mesh when you used TVT products?

A: No.

Q: And have other surgeons ever communicated to you concerns about the mesh used in the TVT products fraying?

A: No.

Q: Losing particles?

A: No.

Q: Curling?

A: No.

Q: Roping?

A: No.

...

Q: Did you ever in your surgical practice notice a difference in performance or outcomes between laser- or mechanically-cut mesh?

A: No.

Ex. 1, Ramsey 4/6/16 Dep. Tr. 190:6-21; Ex. 2, Ramsey 4/7/16 Dep. Tr. 392:13-16. In addition, his experience has permitted Dr. Ramsey to compare his experience to that of his colleagues and the published medical literature. Ex. 2, Ramsey 4/7/16 Dep. Tr. 391:16-392:5, 393:15-22.

As this Court recognized in other cases, it is an acceptable and reliable methodology for a physician to draw upon his clinical experience when forming opinions about the safety and efficacy of polypropylene mesh. *Tyree*, 54 F. Supp. 3d at 585; *see also Trevino*, 2016 WL 1718836, at *32; *Winebarger*, 2015 WL 1887222, at *6-7. Dr. Ramsey's clinical experience is no different and has permitted him to observe firsthand the safety and efficacy of the TVT and compare his experiences to the published literature. At the very least, Ethicon asks that the Court to reserve ruling until trial consistent with its earlier ruling as to Dr. Ramsey. *See In re Ethicon, Inc.*, 2016 WL 4582227, at *3.

III. Dr. Ramsey is entitled to testify about risks of implanting mesh and whether those risks appeared in the IFU, and the common knowledge of physicians regarding risks.

Dr. Ramsey's proposed testimony is consistent with this Court's orders. The Court has determined that Dr. Ramsey is qualified to testify "about the specific risks of implanting mesh and whether those risks appeared on the relevant IFU." *In re Ethicon, Inc.*, 2016 WL 4582227, at *4.

Nor is there any barrier to Dr. Ramsey offering opinions about risks that within the common knowledge of physicians. Indeed, although the Court expressed no opinion about expert testimony regarding "whether certain risks were common knowledge," it did not exclude this expert testimony. *See, e.g., In re Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4582231, at *3 n.2 (S.D.W. Va. Sept. 1, 2016) ("The plaintiff's Motion focuses on whether Dr. Woods is qualified to testify about what should be included in or what may be excluded from an IFU. So I offer no opinion on whether Dr. Woods may testify about whether certain risks were common knowledge."); *In re Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4557036, at *3 n.2 (S.D.W. Va. Aug. 31, 2016) (same as to Dr. Drolet); *In re Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL

4536875, at *4 n.2 (S.D.W. Va. Aug. 30, 2016) (same as to Dr. Serels); *In re Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4542054, at *3 n.2 (S.D.W. Va. Aug. 30, 2016) (same as to Dr. Elser); *In re Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4536872, at *3 n.2 (S.D.W. Va. Aug. 30, 2016) (same as to Dr. Sepulveda-Toro); *In re Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4493666, at *4 n.2 (S.D.W. Va. Aug. 25, 2016) (same as to Dr. Toglia); *In re Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4493681, at *3 n.2 (S.D.W. Va. Aug. 25, 2016) (same as to Dr. Pramudji).

Dr. Ramsey is qualified to provide this testimony. As detailed in Ethicon's Wave 1 response, which Ethicon incorporates here, Dr. Ramsey has extensive clinical experience with native-tissue surgical procedures, surgical procedures involving mesh, and mesh repairs. *See* Defs.' Resp. (Dkt. 2263) at 2-4. He has performed approximately 1,000 surgeries, of various types, to correct stress urinary incontinence (SUI) (*see* Ex. G to Pls.' Mot. (Dkt. 2117-7), Ramsey Report at 2; Ex. 2, Ramsey 4/7/16 Dep. Tr. 304:2-17), has treated complications as a specialty (*see* Ex. 1, Ramsey 4/6/16 Dep. Tr. 73:2-7), and trained surgeons in sling procedures (*see* Ex. G to Pls.' Mot. (Dkt. 2117-7), Ramsey Report at 1). He has been a preceptor for midurethral sling professional education on TVT, including giving didactic lectures, instructing cadaver labs, and teaching on the IFU. *Id.* at 16-17. In addition to his clinical experience with mesh surgical techniques and review of IFUs, Dr. Ramsey relies on his review of complications reported in the medical literature, medical conferences, statements of leading medical societies, discussions with other surgeons, and general knowledge as a surgeon. *Id.*; Ex. 2, Ramsey 4/7/16 Dep. Tr. 391:11-392:5; 394:23-395:21.

As a practicing surgeon who went through years of medical education and training, has extensive clinical experience with pelvic-floor surgeries, teaches other physicians about these surgeries, and keeps up with the medical literature, Dr. Ramsey is uniquely qualified to offer opinions about what is within the common knowledge of physicians who perform pelvic-floor surgeries. Indeed, only a physician with such training and experience *could* testify as to common knowledge of surgeons who perform these surgeries.

Because Dr. Ramsey has the qualifications and requisite foundation, he should be able to offer his opinion that risks of mesh surgery are commonly known and that the only risk unique to the midurethral sling is mesh exposure (Ex. G to Pls.’ Mot. (Dkt. 2117-7), Ramsey Report at 16-17; Ex. 1, Ramsey 4/6/16 Dep. Tr. 114:5-21) just as he should be able to testify that wound complications and suture erosions occur with non-mesh SUI surgeries (Ex. G to Pls.’ Mot. (Dkt. 2117-7), Ramsey Report at 17). These opinions are consistent with the legal principle that there is no duty to warn of risks commonly known to surgeons who use the device. 21 C.F.R. § 801.109(c) (providing that information may be omitted from labeling for a prescription device “if, but only if, the article is a device for which directions, hazards, warnings, and other information are commonly known to practitioners licensed by law to use the device”).¹

Thus, Ethicon respectfully requests that this Court deny Plaintiffs’ motion to the extent it seeks to exclude Dr. Ramsey’s testimony regarding risks of mesh surgery that are within the common knowledge of physicians as well as whether certain risks were included in the IFU.

¹ Moreover, this testimony will be helpful to juries assessing warning adequacy because a manufacturer has no duty to warn of risks commonly known to the surgeons who use the device. As stated generally in the Restatement (Third) of Torts: Products Liability § 2, cmt. j, a product seller “is not subject to liability for failing to warn or instruct regarding risks and risk-avoidance measures that should be obvious to, or generally known by, foreseeable product users.” *See also* Restatement (Second) of the Law of Torts §§ 388(b), 402A, cmt. j.

CONCLUSION

For the foregoing reasons, Ethicon respectfully requests that Plaintiffs' motion be denied in its entirety or limited as set forth above.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on October 10, 2016, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

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